K042891

JUN 29 2005

Premarket Notification 510(k) Summary
As required by section 807.92
Datex-Ohmeda OXY-AFR Sensor

GENERAL COMPANY INFORMATION as required by 807.92(a)(1)

COMPANY NAME/ADDRESS/PHONE/FAX:

Datex-Ohmeda, Inc
1315 W Century Dr
Louisville, Colorado 80021 USA
FDA Registration No.1719176.
Tel: 303-666-7001
Fax: 303-665-9176

NAME OF CONTACT:

Mr. Joel Kent
Datex-Ohmeda
86 Pilgrim Road
Needham, MA 02492 USA
Tel: 781-449-8685
Fax: 781-433-1344

DATE:

October 17, 2004

DEVICE NAME as required by 807.92(a)(2)

TRADE NAME:

Datex-Ohmeda OXY-AFR Sensor

COMMON NAME:

Reprocessed Pulse Oximetry Sensor

CLASSIFICATION NAME:

The following Class II classifications appear applicable:

73 NLF	(Reprocessed) Oximeter	21 CFR 870.2700

NAME OF LEGALLY MARKETED DEVICE FOR WHICH A CLAIM OF SUBSTANTIAL EQUIVALENCE IS MADE as required by 807.92(a)(3)

The Datex-Ohmeda OXY-AFR Sensor is substantially equivalent in safety and effectiveness to the legally marketed (predicate) Datex-Ohmeda OXY-AF SENSOR (K021265).

DEVICE DESCRIPTION as required by 807.92(a)(4)

This OXY-AFR sensor has a sensor head, consisting of a red LED and two infrared LEDS mounting on a leadframe, wired to a detector with a 1 meter cable and custom "happisnap" connector. There are two optical windows where the LED light is transmitted between the detector and LEDS. These components are packaged in a heat sealed package. The OXY-AFR is identical to the OXY-AF sensor with the exception of the new patient window adhesive. The OXY-AFR Sensor is for use in small adult and pediatric patients in the hospital, ICU, anesthesia, respiratory therapy, and during transport.

The Datex-Ohmeda OXY-AFR Sensor has the following differences when compared to the Datex-Ohmeda OXY-AF predicate device. The OXY-AFR sensor is a reprocessed OXY-AF sensor During reprocessing the used OXY-AF sensor is tested, cleaned, inspected and decontaminated. After decontamination new patient adhesive is installed over the optical windows and the reprocessed sensor is repacked with new removable tape. The OXY-AFR Sensor and the predicate OXY-AF SENSOR have the same performance specifications. The changes in the labels and instructions for use were made to add the reprocessed part numbers and name of the new device to the IFU. No changes in the warnings, cautions or contraindications have been made.

INTENDED USE as required by 807.92(a)(5)

Intended use:
The reprocessed AllFit Oximetry sensor, OXY-AFR, is a single-patient-use, adhesive sensor for short-term or long-term monitoring of functional oxygen saturation and pulse rate

Indications for use:
The reprocessed AllFit Oximetry sensor, OXY-AFR, is a single-patient-use, adhesive sensor for short-term or long-term monitoring of functional oxygen saturation and pulse rate. The device is indicated for use by qualified medical personnel only.

SUMMARY OF TECHNOLOGICAL CHARACTERITICS OF DEVICE COMPARED TO THE PREDICATE DEVICE as required by 807.92(a)(6)

The Datex-Ohmeda OXY-AFR Sensor is substantially equivalent in safety and effectiveness to the legally marketed (predicate) Datex-Ohmeda OXY-AF SENSOR (K040831).
The Datex-Ohmeda OXY-AFR Sensor has the following similarities to the Datex-Ohmeda OXY-AF SENSOR predicate device:
-have the same indicated use
-have the same fundamental scientific technology and use the same operating principle
-are manufactured using the same processes
-constructed of identical materials except for the patient window adhesive which is equivalent to the original window adhesive
The Datex-Ohmeda OXY-AFR Sensor has the following differences when compared to the Datex-Ohmeda OXY-AF SENSOR predicate device:
-The OXY-AFR sensor is a reprocessed OXY-AF sensor.
-The patient window adhesives are different but equivalent.
In summary, the Datex-Ohmeda OXY-AFR Sensor, described in this submission is substantially equivalent to the predicate OXY-AF SENSOR (K040831).

SUMMARY OF NONCLINICAL TESTING FOR THE DEVICE and CONCLUSIONS as required by 807.92(b)(1)(3)

Datex-Ohmeda OXY-AFR Sensors are normally used and installed by a trained nurse or doctor. Necessary precautions and warnings are stated on the instructions for use. The Verification and Validation data, safety testing report and Accuracy testing is included.
The decontamination process validation was conducted and this report is included.
Biocompatibility summary and testing reports are included as well.

CONCLUSION:

The summary above shows that there are no new questions of safety and effectiveness for the Datex-Ohmeda OXY-AFR Sensor as compared to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 9 2005

Mr. Joel C. Kent
Manager, Quality and Regulatory Affairs
GE Healthcare
86 Pilgrim Road
Needham, Massachusetts 02492

RE: K042891
Trade/Device Name: Datex-Ohmeda OXY-AFR Sensor
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: NLF
Dated: May 17, 2005
Received: May 18, 2005

Dear Mr. Kent:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu S. Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: Datex-Ohmeda OXY-AFR Sensor

Indications for Use:

The reprocessed AllFit Oximetry sensor, OXY-AFR, is a single-patient-use, adhesive sensor for short-term or long-term monitoring of functional oxygen saturation and pulse rate. The device is indicated for use by qualified medical personnel only.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number K042891